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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,194	04/23/2001	Timothy P. Croughan	98A9-USCROUG	2938

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PATENT DEPARTMENT
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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

16

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,194

Applicant(s)

CROUGHAN, TIMOTHY P.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9,11,13-15,31,38,54,61,129-132,134-136,138,140-146,148-150,152,154-160,162-164,166 and 168-185 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

U.S. Patent and Trademark Office
PTO-326 (Rev. 04-01)

Office Action Summary

Part of Paper No. 16

Continuation of Disposition of Claims: Claims pending in the application are 1-5,7-9,11,13-15,31,38,54,61,129-132,134-136,138,140-146,148-150,152,154-160,162-164,166 and 168-185.

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment filed on 16 May 2003.
2. The Examiner has noted the Affidavit Of Inventor Timothy P. Croughan, filed on 16 May 2003. The Croughan Affidavit appears to support the amendment of the claims deleting specific herbicides, and supports the scope of resistance of the exemplified PTA-904 rice plant.
3. The response has overcome the rejections under 35 USC § 112, first and second paragraphs as directed to the deposit of biological materials (page 15 of the response).
4. The rejection of the pending claims as indefinite under 35 USC § 112, second paragraph, as directed to the phrase "is a derivative of the plant" at claim 1(b), is withdrawn in view of Applicant's arguments and clarification on pages 5-6 of the Remarks.
5. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

7. Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166 and 168-185 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 10 March 2003. Applicant's arguments filed 16 May 2003 have been fully considered but they are not persuasive.

The issue concerning the ATCC Accession Number PTA-904 is now moot, Applicant has amended the specification to clearly indicate that PWC16 has been deposited as PTA-904, this amendment is not considered new matter in the instant case.

Applicant argues that the specification in fact describes a correlation between the structure and the function of the claimed rice plants and that the structure-function "question" is only subsidiary (page 8, 2nd and 3rd paragraphs). This argument is not found to be persuasive because Applicant admits that the resistance mechanisms of the new rice lines have not yet been fully characterized (page 7, 3rd paragraph of the specification). Hence, Applicant invites experimentation by one of skill in the art to determine what Applicant has in fact described. Applicant cites MPEP § 2163 which states "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that **one of skill in the art can reasonably conclude that the inventor had possession of the claimed invention.**" (page 8, 3rd paragraph of the Remarks). The Examiner does not argue that Applicant was in possession of rice variety PWC16 (ATCC Accession No. PTA-904), but that Applicant had not adequately described the genus of progeny plants having the herbicide resistance of PWC16 as broadly claimed. In addition, in Applicant's response

on page 6, Applicant clearly intends the claimed invention to encompass plants “genetically-engineered derivative of that plant (PWC16)” which Applicant admits have not been described as outlined above.

Applicant argues that determining the herbicide resistance characteristics of a particular line of a crop plant can only be described as routine and that comparing the AHAS-acting herbicide resistance characteristics of any particular rice line to those of PTA-904 may readily be conducted through routine experimentation (page 9, 5th paragraph of the Remarks). This argument is not found to be persuasive because the description of the herbicide resistance characteristics of PTA-904 does not adequately describe “derivative” plants. If such a “derivative” rice plant is heterologous for AHAS with two different mutations, the herbicide resistance characteristics of PTA-904 would be masked. In addition, Applicant does not describe how the genetic background of PTA-904 influences these herbicide resistance characteristics.

Applicant argues that before the inventions described in the present application were reduced to practice, no source of AHAS herbicide resistance in rice was known and thus a rice plant that has the herbicide resistance characteristics of PTA-904 should be presumed to be derived from PTA-904 (page 10, 1st paragraph of the Remarks). This argument is not found to be persuasive for the reasons give above.

Applicant argues that it should be kept in mine that it is nearly universal practice that the developer or breeder of a new rice cultivar will disclose publicly the ancestry of the variety (page 10, 3rd paragraph of the Remarks). This is not found to be persuasive because Applicant is assuming diligence of a third party.

Applicant argues that, as directed to PTA-904, the patent law imposes no requirement that an inventor must understand why an invention works, it suffices that the invention does in fact work (page 11, 3rd paragraph of the Remarks). This argument is more relevant to the scope of enablement, which is addressed below.

The Affidavits of inventor Timothy P. Croughan, filed 2 January 2003 and 16 May 2003 have been considered. Applicant argues that said Affidavits clearly confirm that the herbicide resistance of linePTA-904 is due to a mutant AHAS enzyme (page 11, 4th paragraph of the Remarks). This argument is not found to be persuasive, the Examiner maintains that Applicant has failed to establish an adequate written description on a functional-structural basis by which one of skill in the art would recognize that Applicant was in possession of the invention as broadly claimed.

8. Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166 and 168-185 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the herbicide resistant rice plant 'PWC16' (deposited as ATCC Accession Number PTO-904) and methods of using same, does not reasonably provide enablement for any "derivative" or progeny of said deposited rice plant, any rice plant having the herbicide resistance characteristics of the plant 'PWC16' (deposited as ATCC Accession Number PTO-904) or methods of using such "derivative" or progeny rice plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action

mailed 10 March 2003. Applicant's arguments filed 16 May 2003 have been fully considered but they are not persuasive.

The Examiner has addressed the issue of "derivative" plant above, Applicant's argument on page 13, 1st and 2nd paragraph of the Remarks are addressed.

Applicant argues that determining the herbicide resistance characteristics of a particular line of a crop plant can only be described as routine (paragraph spanning pages 13-14 of the Remarks). This argument is not found to be persuasive because the issue of undue experimentation is directed to a derivative plant or progeny plants, of undetermined generations, of the exemplified PTA-904 rice plant. The teaching of herbicide resistance characteristics of PTA-904 does not adequately teach one of skill in the art how to make and use derived or progeny plant as broadly claimed.

Applicants correction of herbicide resistant characteristics as directed to the elected invention are noted (page 14 of the Remarks).

Claim Rejections - 35 USC § 102/103

9. Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166 and 168-185 remain rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Terakawa *et al* 1992 (Japan. J. Breed. 42:267-275). This rejection is repeated for the reason of record as set forth in the last Office action mailed 10 March 2003. Applicant's arguments filed 16 May 2003 have been fully considered but they are not persuasive.

Applicant argues that that bensulfuron methyl does not normally inhibit the growth of a rice plant (page 16, 3rd paragraph of the Remarks). This argument is not

found to be persuasive because Terakawa *et al* disclose at page 268, first paragraph, that "BSM toxicity to rice is not severe, it affects to the initial growth of the rice plants", but "severe" and "would normally inhibit the growth of the rice plant" are relative depending upon the rate of herbicide application. Terakawa *et al* clearly disclose that at a rate of 0.03 mM BSM the mutant rice plants are resistant to a level that would inhibit the growth of a rice plant (see page 271, Tables 2 and 3). It was known in the art at the time of Applicant's invention that mutations in the AHAS enzyme give rise to resistance to sulfonylurea and/or imidazolinone herbicides, thus without evidence to the contrary, the rice plant of Terakawa *et al* would inherently be resistant to at least one imidazolinone herbicide also, including those listed in the claims of the instant application. Terakawa *et al* disclose a process for controlling weeds in the vicinity of the disclosed rice plant comprising applying a herbicide to the weeds and to the rice plant (page 269). Terakawa *et al* is silent as to the full spectrum of sulfonylurea and imidazolinone herbicides the disclosed plant is resistant to, and to the exact nature of the resistance of the AHAS enzyme, *i.e.* any amino acid substitutions. Likewise, Applicant is silent as to the exact nature of the resistance of the AHAS enzyme in the exemplified PTA-904 rice plant.

The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same, material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the Applicant to provide that the claimed product is different from those taught by the prior art and to establish

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patentable differences. See *In re Best* 562F.2d 1252 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Double Patenting

10. Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166 and 168-185 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62, 64, 66, 68 and 70 of copending Application No. 09/934,973. This rejection is repeated for the reason of record as set forth in the last Office action mailed 10 March 2003. Applicant's arguments filed 16 May 2003 have been fully considered but they are not persuasive.

Applicant argues that "derivative" plants must have the specified herbicide resistance characteristics of PTA-904 (paragraph spanning pages 22-23 of the Remarks). This argument is not found to be persuasive because given the limited guidance by Applicant, the rice plant that is a "derivative" or progeny of PTA-904 would obviously fall within the scope of the claimed invention at claim 62 of the copending application. Because Applicant does not teach the AHAS mutation that produces the specific herbicide resistance characteristics of PTA-904, or the other genetic contributions that produces said characteristics, the invention of the instant Application would have been *prima facie* obvious to one of ordinary skill in the art in view of the claimed invention in the copending application.

Applicant argues that claim 1 of the instant application and claim 62 of the copending application stand in the relation of species and genus, respectively (page 25

of the Remarks). This argument is not found to be persuasive because given the teachings of both the instant specification and that of the copending application, it is unclear where the species lies within the genus, the instant situation is more directed to a genus and subgenus relationship.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Amy Nelson". The signature is fluid and cursive, with the first name "Amy" and last name "Nelson" clearly distinguishable.

David H. Kruse, Ph.D.
5 August 2003

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600